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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,851	04/07/2006	Wim Meutermans	MJW-5066-6	9185

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EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
12/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,851	MEUTERMANS ET AL.	
	Examiner	Art Unit	
	Lawrence E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September1, 2009 (Amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

No claims have been cancelled, claims **1-13 and 16-38** have been amended, the disclosure has not been amended, the Abstract has been amended, and new claims **29-42** have been added as per the amendment filed September 30, 2009. No additional or supplemental Information Disclosure Statements (IDSs) have been filed as of the date of this Office action.

Examiner's previous review of the claims revealed two claims numbered "**35.**" Applicant has correctly noted that the instant Image File Wrapper includes two page 56 images leading to this incorrect conclusion. In view of the new set of claims now of record wherein there is no page duplication or consequent claim duplication, this matter is considered properly addressed and no further action is found to be necessary. .

Claims **1-42** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **1-42** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for the substantial number of compounds synthesized and tested and the pharmaceutical compositions thereof, does not reasonably provide enablement for the generic assertion that the much larger generic class of compounds, method of medicinal treatment wherein same are administered, or the pharmaceutical compositions thereof. In addition, examiner notes that the claim **1** is directed to a generic class of pharmaceutical activities ("inhibiting or effecting the activity of a [G-protein coupled receptor] (GPCR)" with some specific receptors being included as therapeutic targets in dependent claims, but that no specific disease conditions are listed in the claims as being effectively treated by administration of any single compound, or "combination" of compounds, disclosed herein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims is found to be excessive because of reliance on numerous variables to be applied to the generic structure to generate a vast array of species, the vast majority of which are not synthesized herein or tested for any disease-specific medicinal activity herein.

B. The nature of the invention: The invention is apparently directed to the treatment of diseases associated with the "GPCR" receptor set (scope undefined) by the administration of compounds as defined by "General Formula I" and to pharmaceutical compositions wherein the active ingredient is also defined by the same General Formula.

C. The state of the prior art: No prior art references presently of record are cited below as anticipating the instant claimed subject matter in view of amendments now of record.

D. The level of one of ordinary skill: One of ordinary skill would be expected to be familiar with the synthesis of the carbohydrate derivatives claimed as active ingredients herein, and also familiar with the test protocols applied to establish GPCR binding affinity. Examiner assumes that the terms GPCR found herein and "G-protein linked receptors" or "GPLR" found in the prior art patents cited below refer to essentially the same subject matter.

E. The level of predictability in the art: This instant art area is presumed to be unpredictable because of the absence of any clear showings that compounds disclosed herein or compounds disclosed in the prior art are effective in the treatment of any diseases.

F. The amount of direction provided by the inventor: The instant disclosure provides directions concerning synthesis of the compounds listed in the claims, and provides some indication that GPCR binding occurs, but does not provide any connection between the latter data and the effective treatment of any disease condition.

G. The existence of working examples: This subject is dealt with in the previous paragraph.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is found to be excessive because the instant disclosure, while providing a lengthy list of compounds and some receptor binding data, does not provide any showing that clearly establishes that the instant claimed method is effective in the treatment of

any disease condition, or that the excessive breadth of the compounds asserted to have the claimed activity has been adequately enabled by the instant disclosure.

Applicant's arguments filed September 30, 2009 have been fully considered but they are not persuasive.

Applicant has argued that the amendments now of record have rendered the above rejection open to reconsideration. Examiner has reviewed the rejection and the claims as amended, and notes a continuing uncertainty concerning the nature of the invention that applicant apparently has argued is enabled. Examiner notes with interest the preamble term "method of inhibiting or effecting the activity of a G-Protein Coupled Receptor (GPCR)," a term that fails to define any particular receptor or any particular involvement of one or more receptors in the treatment of any particular disease condition. Said term does not even assert that "inhibiting" is the only possible outcome, implying that administration of an active ingredient as defined in claim **1** may actually cause the host being treated additional undefined difficulties; e.g. the opposite of "inhibiting." Examiner notes the newly cited **Kroeze et al.** reference (PTO-892 ref. R), at pages 4868, column 3 through page 4869, column 1. In this portion of its analysis **Kroeze et al.** discloses that there is considerable research interest in the area of cell receptors, but that there is an absence of predictable connections between any particular receptors and the effective treatment of any particular medical condition(s), a conclusion supported by disclosure of the large proportion of "orphan" receptors wherein no connection of the behavior of the receptor with any particular disease-related cellular process has been established.

Examiner finds that this same problem afflicts the instant disclosure and claims, and is the reason why examiner finds that the above rejection continues to be valid. For this reason the instant rejection has been maintained.

Claims **1-42** are objected to because of the following informalities:

In claims **16-38** the term "defined as follows" is incomplete. Examiner respectfully suggest that a colon (**-- : --**) should be added to the end of the noted term to make said term grammatically complete.

In claims **1-17 and 39-42** the claims have failed to identify -- administration to a host in need thereof --.

Appropriate correction is required.

Claim **2** is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **2** the Markush group beginning at line 2 is populated with substituent groups and also with terms that refer to generic classes of compounds; e.g. "amidine," "imine," "carboxylic acid," "phosphate," "hydroxamic acid," etc., etc. Applicant is respectfully requested to rename all compound names as substituent names or delete as appropriate.

Applicant's arguments filed September 30, 2009 have been fully considered but they are not persuasive.

Applicant has requested additional explanation of the rejection repeated above. Applicant is respectfully requested to note that substituent groups (e.g. methyl, ethyl, hydroxyl, etc.) are definitionally distinct from classes of compounds (alkanes, alcohols, etc.), the latter being well represented in claim **2** by terms including those quoted above. Examiner assumes that applicant intended substituents, not mixtures of compounds, and therefore respectfully requests an amendment that recognizes that substituents are named differently that the compounds from which said substituents have been derived. Appropriated correction is respectfully requested.

The previously presented rejections over prior art have been reconsidered in view of applicant's amendments wherein the compounds of the cited prior art are no longer present within the scope of the amended claims. Said rejections have therefore been rendered moot and for this reason have been withdrawn.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA

1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-42** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1, 2 and 4-29*** of copending Application No. **10/524,048**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients in the pharmaceutical compositions herein (claim **38**) are directed to substantially overlapping subject matter when compared with the compounds of the cited **'048** application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **1-38** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendments.

Claims **1-42** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-3, 5-9, 12-21 and 24-30*** of copending Application No. **11/664,632**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients in the pharmaceutical compositions herein (claim **38**) are directed to substantially overlapping subject matter when compared with the library of compounds of the cited **'632** application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **1-38** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendments.

Claims **1-42** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-5, 8-18 and 21-22*** of copending Application No. **11/813,737**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients defined by pharmaceutical composition claim **38** herein are directed to substantially overlapping subject matter when compared with the method of treatment claims, the compound claims and the composition claim of the **737** application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **1-38** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendments.

Claims **1-42** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-20*** of copending Application No. **12/063,920**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients defined herein in the pharmaceutical compositions claim **38** are directed to substantially overlapping subject matter when compared to the compounds identified as having pharmaceutical activity in the claims of the **'920** application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **1-38** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendments.

Claims **1-42** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-9 and 11-24*** of copending Application No. **12/096,771**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients defined in instant claim **38** are directed to substantially overlapping subject matter when compared with the method of treating and the composition claims of the **771** application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **1-38** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendments.

Claims **1-42** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1 and 13-25*** of copending Application No. **12/184,473**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients defined by instant pharmaceutical composition claim **38** are directed to substantially overlapping subject matter when compared with the compound and composition claims in the **'473** application, particularly those claims that claim compounds, including libraries of compounds, with antibacterial activity, and what appear to be claims directed to pharmaceutical compositions thereof..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **1-38** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendments.

Claims **1-42** of this application conflict with claims ***1, 2 and 4-29*** of copending Application No. **10/524,048**, claims ***1-3, 5-9, 12-21 and 24-30*** of copending Application No. **11/664,632**, claims ***1-5, 8-18 and 21-22*** of copending Application No. **11/813,737**,.claims ***1-20*** of copending Application No. **12/063,920**, claims ***1-9 and 11-24*** of copending Application No. **12/096,771**, and claims ***1 and 13-25*** of copending Application No. **12/184,473**. 37 C.F.R. §1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
12/11/2009

/Lawrence E. Crane/

Primary Examiner, Art Unit 1623

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